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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,866	10/21/2003	Benjamin Oshlack	200.1133CON	3333

7590 03/17/2010

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
03/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,866	OSHLACK ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,15,17,19-59 and 61-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-12,15,17,19-59,61,62,64,65 and 67-73* is/are allowed.

6)☒ Claim(s) *66* is/are rejected.

7)☒ Claim(s) *63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/22/09; 11/10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114, the Amendment and Applicant's Arguments/Remarks, all filed 11/10/09 and the Amendment and Supplemental Response filed 12/23/09 is acknowledged. The Information Disclosure Statements (IDS) filed 07/22/09 and 11/10/09 are also acknowledged.

Applicant's arguments, see Response pages 17-19, filed 11/10/09, with respect to the rejection(s) of claim(s) 1-9, 41 and 54 under 35 U.S.C. 112, first paragraph and the rejection of claims 1-59 and 61-73 under 35 U.S.C. §103(a) over Kaiko (US 6,277,384) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of §35 U.S.C 112, 1st paragraph, with respect to claim 66.

Claims 1-12, 15, 17, 19-59 and 61-73 are pending in this action. Claims 1-9, 29, 30, 41, 54 and 62-69 have been amended. Claims 13, 14, 16, 18 and 60 have been cancelled. Claim 66 is rejected. Claim 63 is objected to. Claims 1-12, 15, 17, 19-59, 61, 62, 64, 65 and 67-73 are allowable.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 November 2009 has been entered.

* * * * *

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 07/22/09 and 11/10/09 were filed after the mailing date of the Final Office Action on 07/22/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

* * * * *

Claim Objections

Claim 63 is objected to because of the following informalities:

Claim 63 recites "...any one of claims 1, 2, 3, 4, 7, 8, 9, *14*, 19...". However, claim 14 from which claim 63 can depend, is a cancelled claim.

Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 66, which recites "the oral dosage form of claim 65, wherein the antagonistic effect is prevention of development of

physical dependence to opioids" renders the claims non-enabling. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention/(5) The breadth of the claims:

The nature of the invention is directed to a dosage form comprising (i) an opioid agonist in releasable form and (ii) particles consisting of an opioid antagonist, a sequestering material and one or more pharmaceutical excipients, whereby the dosage form is an oral dosage form wherein the sequestering material separates the antagonist from the agonist and substantially prevents the release of the antagonist from the dosage form which has been administered intact such that an amount of the antagonist released at 1 and 2 hours from the dosage form which has been administered intact is undetectable by High Performance Liquid Chromatography, and less than 15% by weight of the opioid antagonist is released within 36 hours after the administration of the intact dosage form, based on an in-vitro dissolution of the intact dosage form in a dissolution bath; and a ratio of the amount of the antagonist released from the dosage form after tampering to the amount of the antagonist released from the intact dosage form is about 4:1 or greater, based on the in-vitro dissolution of the dosage form at 1 hour in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37 degrees C; wherein the agonist and the particles are interdispersed and are not isolated from each other in two distinct layers (see claim 1).

(2) The state of the prior art:

The prior art teachings provide for compositions comprising the use of opioid antagonists, opioid agonists and sustained release coating materials. The compositions can be in various forms, which include, tablets, capsules, lozenges, emulsions and the like (see for instance, Palermo WO 99/32120).

(3) The relative skill of those in the art:

The relative skill of those in the art is high, such as Ph.D. or M.D. level technology.

(6) The amount of direction or guidance presented:

The specification filed 10/21/03 provides no guidance on how the "prevention" of development of physical dependence to opioids" would be achieved and provided through the use of merely an agonist, antagonist, a sequestering material and additional pharmaceutical excipients, as is instantly claimed (see claims 1 and 66 for instance). In addition, Applicant has not imparted any special definition with respect to the term "prevention" in their specification.

(7) The presence or absence of working examples:

The working examples are insufficient to establish the instant "prevention of development of physical dependence to opioids". The examples are distinct from the scope of the claims and there are no formulations of the claims presented which would be representative of the examples shown in the instant specification.

(8) The quantity of experimentation necessary:

When the above factors are weighed together, it is the position of the Examiner that the instant invention would require 'undue' and painstaking experimentation to arrive at the instant invention to determine which particular combination of ingredients and in which particular amounts and/or ratios would be needed to "prevent" the development of physical dependence to opioids as is instantly claimed by Applicant.

It is suggested that this limitation which incorporates "prevention" be deleted to overcome this rejection.

* * * * *

Response to Arguments

Applicant's arguments, see Response pages 17-19, filed 11/10/09, with respect to the rejection(s) of claim(s) 1-9, 41 and 54 under 35 U.S.C. 112, first paragraph and the rejection of claims 1-59 and 61-73 under 35 U.S.C. §103(a) over Kaiko (US 6,277,384) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of §35 U.S.C 112, 1st paragraph, with respect to claim 66.

Conclusion

Claim 66 is rejected.

Claim 63 is objected to.

Claims 1-12, 15, 17, 19-59, 61, 62, 64, 65 and 67-73 are allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

March 15, 2010